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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0562]

Compliance Policy Guide Sec.110.300—"Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance policy guide (CPG) Sec. 110.300 entitled "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002." The CPG provides written guidance to FDA's staff on enforcement of section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency's implementing regulation, which require, beginning on December 12, 2003, registration with FDA for all domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States.

DATES: This guidance is final upon the date of publication. However, you may submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-

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addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Food for human consumption: Judith Gushee, Division of Enforcement, Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 301–436–2417.

Food for animal consumption: Isabel Pocurull, Division of Animal Feeds, Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration, 301–827–0175.

SUPPLEMENTARY INFORMATION:

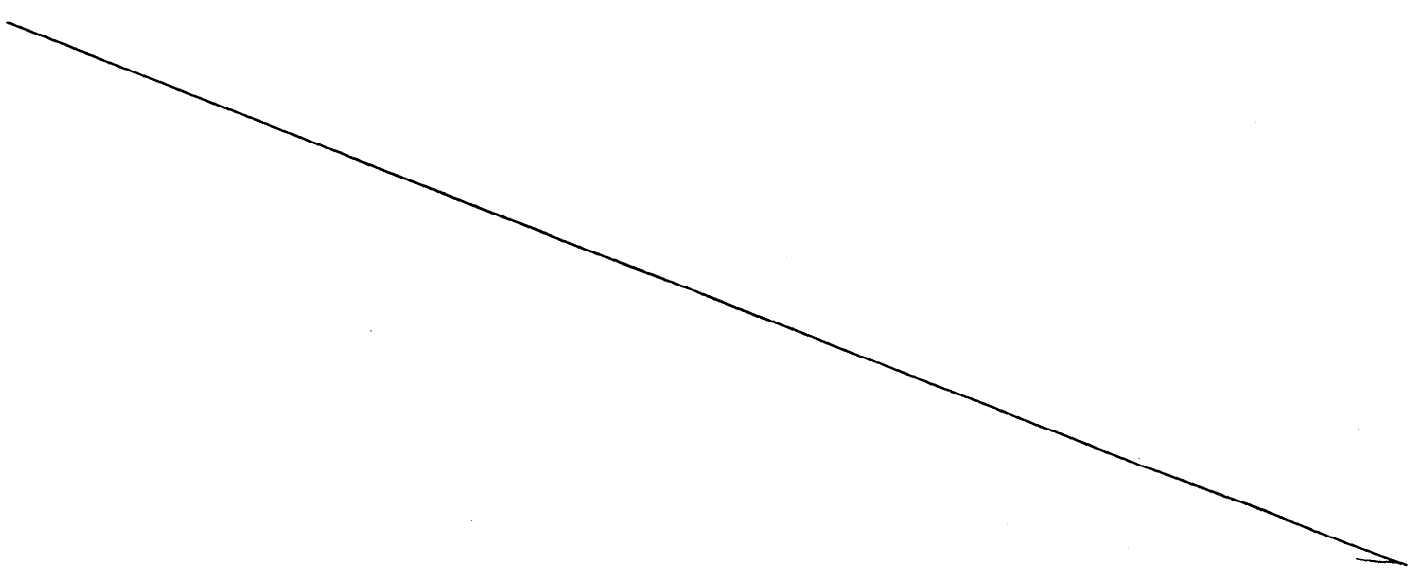
I. Background

FDA is announcing the availability of CPG Sec.110.300 entitled "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002." This guidance outlines for FDA staff the agency's policy on enforcement of section 305 of the Bioterrorism Act and its implementing regulation (68 FR 58894, October 10, 2003; to be codified at 21 CFR part 1, subpart H). The Bioterrorism Act and subpart H require that, beginning on December 12, 2003, all domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States be registered with FDA.

FDA is issuing this document as level 1 guidance consistent with FDA's good guidance practices regulation § 10.115 (21 CFR 10.115). The CPG Sec. 110.300 is being implemented immediately without prior public comment, under § 10.115(g)(2), because the agency has determined that prior public participation is not feasible. As noted, under section 305 of the Bioterrorism Act, the requirement that food facilities be registered is effective December 12, 2003, making it urgent that the agency explain how it intends to enforce this requirement.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

An electronic version of this guidance is available on the Internet at *http://www.fda.gov/ora* under "Compliance References."

Dated: December 16, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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